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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



### DETAILED ACTION

Receipt of amendment and remarks dated 10-24-05 is acknowledged.

Claims 1-24 are pending in the present application.

In response to the amendment, the following is a new rejection applied to the claim 4:

#### ***Claim Rejections - 35 USC § 112***

1. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant claim recites the new limitation "provided that at least one of D'1, D"2, D"1 and D2 is not OH", which is not supported by the specification. Applicants state that page 6 and page 10 provide support for the claimed limitation. However, a careful review of the specification does not reveal any support for the newly added limitation. Accordingly, the claim limitation is a new matter.

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim recites the new limitation "provided that at least one of D'1, D"2, D"1 and D2 is not OH" is vague and indefinite because the limitation recites the variable D"2 twice and it is not clear if applicants intend to claim D'2 and D"2. If so, appropriate correction is requested.

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The following rejection of record has been maintained:

***Claim Rejections - 35 USC § 103***

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53951 (WO).

WO '951 teaches terminally-branched polymeric linkers and polymeric conjugates containing the linkers for forming long-acting conjugates of bioactive materials. In particular, WO teaches compounds of formula I (page 3), where the variables J, E, Y, M, Z etc., (described on pages 3-5). Furthermore, the compounds listed on pages 9-10 meet the claimed compound, particularly, the compound of claim 3. WO further teaches that R1 is a polymeric residue, which includes polyalkylene oxides such as polyethylene glycols (page 12); and also teaches the molecular weight of polymers in the range 2,000 to 100,000 (page 13, lines 15-25). WO also teaches the linking a number of drugs such as podophyllotoxin, gemcitabine, ciclopirox etc to be delivered with the prodrug compounds (page 16-17). The conjugated prodrugs of WO are described on pages 24, which read on the instant claimed prodrugs (claim 18). WO differs from the instant claims in the presence of [R2-C-R3]<sub>m</sub>, which is not present in the claimed compound. However, WO teaches q=zero or positive integer (page 4, line 19). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use q as 0 or positive integer and still achieve a prodrug having same efficiency in delivering the desired drug.

***Response to Arguments***

Applicant's arguments filed 10-24-05 have been fully considered but they are not persuasive.

Applicants argue that while previously presented claims require that D1 and D2 both cannot be OH, the present claims (amended) clarify that at least one of D'1, D"2, D"1 and D2 is not OH, which require the terminal groups to include at least one of moiety IV and V that facilitate the benzyl-elimination reaction to regenerate or release the drug or biologically active moiety attached thereto. It is argued that there is no disclosure in the cited reference to provide the specific moieties of IV and V, as required by the newly added limitation. Applicants' arguments are not persuasive because the present amendment is only limited to claim 4 and not to all the claims. With respect to claim 4, please refer to the new matter rejection. Because claims 1-3 and 5-22 are not limited by the newly added claims, the argument that the claims are unobviousness over the prior art teachings is not persuasive. Accordingly, the rejection is maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lakshmi S Channavajjala  
Examiner  
Art Unit 1615

January 6, 2006

  
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SUPERVISORY PATENT EXAMINER  
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